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NIXON & VANDERHYE, PC			EXAMINER	
901 NORTH GLEBE ROAD, 11TH FLOOR			MARX, IRENE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/821,025	Applicant(s) BIJL ET AL.
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

1) Responsive to communication(s) filed on 11 February 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 68,72,76-78,80,83,85-95 and 113-172 is/are pending in the application.
 4a) Of the above claim(s) 96,113,130-148 and 161-172 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 68,72,76-78,80,83,85-95,114-129 and 149-160 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

The amendment filed 2/11/089 is acknowledged. Applicant indicates that claims 68, 72, 76-78, 80, 83 and 85-172 are pending. However, claims 84 and 97-112 are cancelled.

Claims 68, 72, 76-78, 80, 83, 85-95, 114-129 and 149-160 are being considered on the merits.

Claims 96, 113 and claims 130-148 as well as newly presented claims 161-172 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Upon reconsideration, the new matter rejection is no longer maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 150 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 150 fails to find proper antecedent basis for "dry matter content of 25% to 80%".

Claim 149 is directed to "average dry matter content of at least 80%".

Claim 150 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

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in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68, 72, 76-78, 80, 83, 85-95, 114-129 and 149-160 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Akimoto *et al.* (U.S. Patent No. 4,916,066) taken with Barclay (U.S. Patent No. 5,656,319) and Huang *et al.* (U.S. Patent No. 4,0566,38) and further taken with Langejan (U.S. Patent No. 3,843,800) and Groenendaal (U.S. Patent No. 5,716,654)

Akimoto *et al.* teach a dry *Mortierella* composition (See, e.g., col. 8, lines 7-12).

The reference differs from the claimed invention in that the dried composition is not in extruded granule form. However, Barclay teaches a related microbial composition containing fatty acids wherein the composition is extruded. See, e.g., bridging paragraph between col. 11 and 12. The reference recognizes the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion. In addition, Huang *et al.* teach extruded granules of fungi such as *Aspergillus* which are subsequently dried. See, e.g., bridging paragraph between col. 2 and 3, and col. 3, lines 11-17. The extruded material would reasonably be expected to be porous as claimed, to have the degree of dryness required and to have the dimensions as claim designated.

In addition, Langejan teaches a dry yeast preparation prepared by extrusion and having the required dimensions and porosity. See, e.g., Example 1. The yeasts in this preparation are active initially, but as indicated by Groenendaal lose activity and are dead. See, e.g., col. 1, lines 45-67.

The properties of the dried *Mortierella* as far as oil content and sizing discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of composition properties for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Inasmuch as Langejan discloses a fungal product that is granular, porous and has the appropriate dimensions, one of ordinary skill in the art would reasonably have expected that

similar extruded products containing other fungi, such as *Mortierella*, that are known producers of important fatty acids, as disclosed by Barclay, would similarly provide the advantages of an extruded product regarding reduction of drying time and costs as well as an increase in the bioavailability of the fatty acids upon extrusion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the dried *Mortierella* product of Akimoto *et al.* by submitting the biomass to an extrusion and drying process as disclosed by Barclay, Huang *et al.*, Langejan and Groenendaal in view of the expected economic benefits of obtaining a dried stable microbial product that is easy to manipulate and the cost of which is reduced.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's contention that the office has not established that all limitations are known in the prior art is noted. Yet, applicant has not identified any particular limitations that distinguish the claimed granule composition over similar granule compositions known in the art. For example, the dry matter content, the porosity and the size are all readily adjustable by one of ordinary skill in the art of drying microorganisms and of extrusion and vary widely throughout the claim designated invention. Applicant has not demonstrated with objective evidence that any of the various limitations as claimed are critical for the various compositions as claimed.

Applicant asserts that "impending solvent penetration during extraction is a problem avoided by the claimed invention", yet applicant has not identified with any specificity which size granule having which porosity does in fact have the touted properties. Moreover, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the various granule compositions taught in the prior art. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433

(CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Only in claims 116, 123, and 150 is a porosity of 15% to 50% required and in dependent claims 154 and 155 it is 20-40% and 25% to 35%, respectively. In most claims the porosity is "generated" by extruding, while in claim 125 "a porosity" is "generated" by drying of granular particles comprising the microorganism. The functional recitation of "have a porosity that allows solvent access" is not seen as a distinguishing property of extruded granules or otherwise dried granules and applicant has not shown otherwise with objective evidence of unexpected results. It is submitted that any extruded composition of dried fungi would "have a porosity that allows solvent access".

As noted previously, the invention reads on "granules" that are of 12 mm diameter and 72 mm in length. Thus the claimed invention ranges from granules that are, for example, 0.1 mm in diameter to 0.2 mm long to those that are 12 mm diameter and 72 mm long. It is submitted that adjustment to such sizes is clearly within the ordinary skill in the art and is not clearly indicative of any particular results. Moreover, the claimed invention of claim 68 is directed to "a dried composition that is stable at room temperature consisting essentially of granules comprising extruded microorganisms which are fungi of the genus *Mortierella*" which in dependent claims 72, 76-78, 80, 83, 85-95 is indicated as "granule composition". In claims 114 the invention is directed to dried granules comprising extruded microorganisms which are fungi of the genus *Mortierella*". In claim 121 the invention is directed to "dried granules comprising ...*Mortierella*, which have a porosity, comprise arachidonic acid and an average dry matter content of 80% or more", etc.

Applicant argues specifically the limitations of claims 94, 121 and 149 regarding "adjustment of conditions". In claim 94 no structural features are provided, but rather "porosity of the granules allows solvent access". In claim 121, the phrase is repeated and it is indicated that the *Mortierella* comprise arachidonic acid in some amount and there is an average dry matter of 80% or more. It is unclear that the dry matter content affects "access to solvent", which, of course, includes water. In claim 149, the porosity is 15-50%, the dry matter has an

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average of at least 80% and the diameter ranges from 0.1 to 12 mm and arachidonic acid is present. Yet in claim 150 the dry matter content can be as low as 25%.

None of the recited features in claims 94, 121 and 149 can be clearly correlated to the functional limitations recited and now touted as distinguishing over the cited references..

It is also important to note that no clear definition of the optimum size for the granules is found in the disclosure.

Applicants arguments directed to "making any oil readily extractable" are puzzling in the context of claims directed to porous granules of dead *Mortierella* which may or may not comprise arachidonic acid optionally contained in lipids. Applicant is arguing an efficient process of extraction of oils from *Mortierella* which the claims are directed to dead *Mortierella* granules or compositions comprising dead *Mortierella* granules. Applicant argues in this regard that the claimed product has "enhanced extractability". Moreover, applicant has not clearly delineated on this record which of the large variety of claimed granule compositions have a structure commensurate with the touted properties. Also there is no clear indication as to the extent of the "enhancement" of extractability in this context. There is no comparison with the cited art. Thus, these arguments have not been substantiated with appropriate evidence.

Specifically, Applicant argues that "Barclay's HUFA extraction process does not involve extruding a biomass and then drying to produce granules **followed by extracting fatty acids from the granules.**" (Emphasis added). However, this argument is irrelevant to the claim designated compositions. With all due respect, the claims are not directed to "using extrusion as part of a process for extracting fatty acids as required by Applicants", Similarly, the claims are not directed to "using an extrusion step in a process for the purification, extraction or isolation of fatty acids" (Response, page 20, paragraph 2). It is emphasized that Akimoto *et al.* teach dried *Mortierella* containing fatty acids capable of being extracted. Therefore, these arguments lack merit and are not clearly relevant to the invention as claimed.

The arguments regarding Example 25 are noted. To begin with, there are two Examples 25. Even though extrusion is mentioned at Example 25 (II), an extrusion procedure is not found in Example 1. Moreover, it is unclear that the touted results of Example 25 pertain with any specificity to the invention as claimed.

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That Langejan and Groenedaal disclose live yeast and address different problems is noted. However, these references are relied upon for their disclosure of a fungal product that is granular, porous and has the appropriate dimensions. Applicant argues that the intended use is different. However, as noted previously, the invention as claimed is not directed with any particularity to a product having distinguishing structural properties as touted and argued.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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